A DOCPHOENIX

Office Action Summary	Application No. 09/849,626	Applicant(s) BANGUR ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/3/01.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4, 8, 11, 15, drawn to nucleic acids, classified in class 536, subclass 23.1. (where claim 11 is limited nucleic acids).

II. Claims 2, 7, 11, 18, drawn to proteins, classified in class 530, subclass 350. (where claim 11 is limited to proteins).

III. Claims 5, 11, 16, drawn to antibodies, classified in class 530, subclass 387.1. (where claim 11 is limited to antibodies).

IV. Claim 6, drawn to methods of immunoassay, classified in class 435, subclass 7.1.

V. Claims 9, 12, 13, 17, as limited to protein therapy, drawn to methods of stimulating T-cells, including methods where the stimulated T-Cells are used to treat cancer, classified in class 424, subclass 184.1.

VI. Claims 9, 12, 13, 17, as limited to antibody therapy, drawn to methods of stimulating T-cells, including methods where the stimulated T-Cells are used to treat cancer, classified in class 424, subclass 130.1.

VII. Claims 9, 12, 13, 17, as limited to gene therapy, drawn to methods of stimulating T-cells, including methods where the stimulated T-Cells are used to treat cancer, classified in class 514, subclass 44.

VIII. Claim 10 and 11, drawn to an isolated T-cell population, classified in class 435, subclass 372.3. (where claim 11 is limited to the isolated T-cells).

IX. Claim 14, drawn to methods nucleic acid analysis, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Groups I, VII, IX and in Groups II, III, IV, V, VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because b the Group I, VII and IX methods are drawn to nucleic acids and methods of using nucleic acids while the Group II, III, IV, V, VI and VII methods are drawn to proteins, to antibodies, to T-cell populations and to methods of using proteins and antibodies. These methods have different modes of operation since the nucleic acid methods utilize nucleic acid hybridization while the protein methods use protein-protein binding. Further, they have different effects since the nucleic acid methods yield information regarding the presence or absence of nucleic acids and the protein methods yield information regarding the status of the proteins. Finally, the proteins and nucleic acids themselves represent structurally different molecules with different chemical characteristics, different methods of making and using and different functions and effects..

3. Inventions in Group I and in Groups VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid product of Group I can be used in the detection method of Group IX, in the gene therapy method of Group VII, in nucleic acid purification methods or in PCR amplification methods.

4. Inventions in Group VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the Gene therapy method of Group VII operates by treatment of a patient with a nucleic acid to result in a treatment for that patient while the nucleic acid analysis method operates by hybridization detection to determine the health status of a patient.

5. Inventions in Groups II, III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the antibodies differ in structure and function and effect from the proteins and the T-cells and the T-cells differ in structure, in function and in effect from both the antibodies and the proteins.

6. Inventions in Group II and in Groups IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with

another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein products can be used in immunoassay methods or in protein therapy methods or in enzymatic assay methods or in purification methods.

7. Inventions in Group III and in Groups IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody products can be used in immunoassay methods or in antibody therapy methods or in enzymatic assay methods or in purification methods.

8. Inventions V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation with the invention of Group V relying on protein stimulation, the invention of Group VI using antibodies to treat T-cells and the invention of Group VII relying on nucleic acid treatment. These are different in mode of operation and function and may result in different effects.

9. Inventions in Group VIII and in Groups V, VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and

materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the T-cells can be made by the method of Group V, the method of Group VI, or the method of Group VII.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Restriction to one of the following inventions is required under 35 U.S.C. 121.

These claims are generic to a plurality of disclosed patentably distinct Inventions each Inventive Group consisting of a different SEQ ID NO. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO for examination even though this requirement is traversed.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the SEQ ID NO inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. A telephone call was made to Jeffrey Hundley on July 19, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

July 19, 2002